

PTQ/SB/OBA (10-01)

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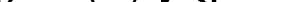
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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT <i>(use as many sheets as necessary)</i>				Complete If Known	
Application Number				09/219,738 09/886,79	
Filing Date				12/22/1998	
First Named Inventor				Thomas E. Tarara et al.	
Art Unit				1615	
Examiner Name				R. Bawa	
Attorney Docket Number				0054.00	

U.S. PATENT DOCUMENTS					
Examiner Initials	Cito No. 1	Document Number Number - Kind Code * (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
WJP	AA	US-4571334	02/18/1986	Yoshisa et al.	11
WJP	AB	US-4765987	08/23/1988	Bonte et al.	11
WJP	AC	US-5032585	07/16/1991	Lichtenberger	11
	AD	US-5262405	11/16/1993	Girod-Vaquez et al.	11
	AE	US-5299566	04/05/1994	Davis et al.	11
	AF	US-5451569	09/19/1995	Wong et al.	11
	AG	US-5527521	06/18/1996	Unger et al.	11
	AH	US-5542935	08/06/1996	Unger et al.	11
	AI	US-5569448	10/19/1996	Wong et al.	11
	AJ	US-5648095	07/15/1997	Jillum et al.	11
	AK	US-5656297	08/12/1997	Bernstein et al.	11
	AL	US-5667808	09/16/1997	Johnson et al.	11
	AM	US-5698537	12/16/1997	Pruss	11
	AN	US-5776496	07/07/1998	Violante et al.	11
	AO	US-5853698	12/29/1998	Straub et al.	11
	AP	US-5853752	05/29/1998	Unger et al.	11
	AQ	US-5853763	12/29/1998	Tice et al.	11
	AR	US-5925334	07/20/1999	Rubin et al.	11
WJP	AS	US-5955143	09/21/1999	Wheatley	11
WJP	AT	US-5985309	11/16/1999	Edwards et al.	11

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Examiner Signature		Date Considered	12/2/02
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¹ Applicant's unique citation designation number (optional). ² See Kinds Codex of USPTO Patent Documents at www.uspto.gov or MPEP 901.04. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

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PTQ/SB/02A (10-01)

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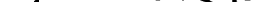
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Substitute for form 1449A/PTO INFORMATION DISCLOSURE STATEMENT BY APPLICANT (use as many sheets as necessary)				Complete if Known Application Number <u>68/219,798</u> <u>09/886296</u> Filing Date <u>12/22/1998</u> First Named Inventor <u>Thomas E. Tarara et al.</u> Art Unit <u>1615</u> Examiner Name <u>R. Bawa</u> Attorney Docket Number <u>0054.00</u>	
Sheet	2	of	2		

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. *	Document Number	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number - Kind Code * (if known)			
JAD	AU	US-6017310	01/25/2000	Johnson et al.	==
	AV	US-6051259	04/18/2000	Johnson et al.	==
	AW	US-6068600	05/30/2000	Johnson et al.	==
	AX	US-6086376	07/11/2000	Moussa et al.	==
	AY	US-6113948	09/05/2000	Heath et al.	==
	AZ	US-6129934	10/10/2000	Egan et al.	==
	BA	US-6165508	12/26/2000	Tracy et al.	==
	BB	US-5707644	11/1997	Illum	==
	BC	US-5306483	4/1994	Mautone	==
	BD	US-5145684	9/1992	Liversidge	==
	BE	US-4358442	11/9/1982	Wirtz-Peritz et al.	==
	BF	US-4404228	9/13/1983	Cloosterman et al.	==
	BG	US-5747001	5/5/1998	Widemann et al.	==
JAD	BH	US-5994318	11/30/1999	Gould Fogerite et al.	==
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JAD		US-			==

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FORM PTO-1049
U.S. DEPARTMENT OF COMMERCE
PATENT & TRADEMARK OFFICE

ATTY DOCKET NO.

0054.10

APPLICATION NO.

09/886,296

INFORMATION DISCLOSURE STATEMENT BY
APPLICANT

(USE SEVERAL SHEETS IF NECESSARY)

APPLICANT

Tarara et al.

FILING DATE

6/21/2001

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1616

EXAMINER INITIAL									DATE	U.S. PATENT DOCUMENTS		CLASS	SUBCLASS	FILING DATE
	D	N	O	C	U	M	E	R	N	T	NAME			
<i>JA</i>	5	3	0	8	6	2	0	A	5/1994	Yen	RECEIVED			
<i>JA</i>	5	5	6	2	6	0	8	A	10/1996	Sekins et al.	SEP 27 2002			
<i>JA</i>	5	6	1	6	3	1	1	A	4/1997	Yen				
<i>JA</i>	5	6	7	3	6	8	6	A	10/1997	Villax et al.	TECH CENTER 1600/2900			
<i>JA</i>	5	6	7	6	9	2	9	A	10/1997	Afchurx et al.				
<i>JA</i>	5	8	2	9	4	3	5	A	11/1998	Rubsamen et al.				
<i>JA</i>	5	8	5	5	9	1	3	A	1/1999	Hones et al.		424	489	
<i>JA</i>	5	8	7	4	0	6	4	A	2/1999	Edwards et al.				
<i>JA</i>	6	0	4	1	7	7	7	A	3/2000	Faithful et al.		128	200.24	

EXAMINER INITIAL									DATE	FOREIGN PATENT DOCUMENTS		CLASS	SUBCLASS	TRANSLATION YES
	D	N	O	C	U	M	E	R	N	T	COUNTRY			
<i>JA</i>	0	2	7	4	4	3	1	A2	7/1988	EPO				
<i>JA</i>	0	3	7	2	7	7	7	A2	6/1990	EPO				
<i>JA</i>	0	6	1	1	5	6	7	A1	8/1994	EPO				
<i>JA</i>	9	6	1	9	1	9	8		6/1996	WO				
<i>JA</i>	9	7	3	6	5	7	4		10/1997	WO				
<i>JA</i>	9	7	3	6	5	7	8		10/1997	WO				

EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)													
	Dallamry et al. "Hollow Porous Particles in Metered Dose Inhalers" Pharm Research 17(2): 168-174 (2000).													
<i>JA</i>	Ahlneck et al. "The Molecular Basis of Moisture Effects on the Physical and Chemical Stability of Drugs in the Solid State" Int. J. of Pharmaceutics 62: 87-95 (1990).													
<i>JA</i>	Altantech et al. "Ca ²⁺ Binding to Phosphatidylcholine Bilayers As Studied by Deuterium Magnetic Resonance. Evidence for the Formation of a Ca ²⁺ Complex with Two Phospholipid Molecules" Biochemistry 23: 3913-3920 (1984).													
<i>JA</i>	Bebincova et al. "Dextran Enhances Calcium-Induced Aggregation of Phosphatidylserine Liposomes: Possible Implications for Exocytosis" Physiol Res 48(4): 319-321 (1999).													
<i>JA</i>	Buckton et al. "The Use of Gravimetric Studies to Assess the Degree of Crystallinity of Predominantly Crystalline Powders" Int. J. of Pharmaceutics 123: 265-271 (1995).													
<i>JA</i>	Buld et al. "Neutron Diffraction Studies on Phosphatidylcholine Model Membranes" J. Mol. Biol. 134: 673-691 (1979).													

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Tarara et al.

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MS	Cevc, G. "Membrane Electrostatics" <i>Biochim Biophys Acta</i> 1031(2): 311-382 (1990)., in particular pp 330-338.
↓	Duzgunes et al. "Studies on the Mechanism of Membrane Fusion. Role of Head-Group Composition in Calcium- and Magnesium-Induced Fusion of Mixed Phospholipid Vesicles" <i>Biochim Biophys Acta</i> 642: 182-195 (1981).
	Ebner et al. "Interactions of Calcium Ions with Phospholipid Membranes" <i>Langmuir</i> 10: 2267-2271 (April, 1994).
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Tarara et al.

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6/-21/2001

GROUP
-4616

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EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	Gordon et al. "Ideal Copolymers and the Second-Order Transitions of Synthetic Rubbers. 1. Non-Crystalline Copolymers" <i>J. Appl. Chem.</i> 2: 493-500 (Sept., 1952).
	Hancock et al. "Characteristics and Significance of the Amorphous State in Pharmaceutical Systems" <i>J. of Pharmaceutical Sciences</i> 66(1): 1-12 (Jan., 1977).
	Hancock et al. "The Relationship Between the Glass Transition Temperature and the Water Content of Amorphous Pharmaceutical Solid." <i>Pharm Research</i> 11(4): 471-477 (1994).
	Hauser et al. "Comparative Structural Aspects of Cation Binding to Phosphatidylserine Bilayers" <i>Biochim Biophys Acta</i> 813: 343-346 (1985).
	Hauser et al. "Interactions of Divalent Cations with Phosphatidylserine Bilayer Membranes" <i>Biochemistry</i> 23: 34-41 (1984).
	Huster et al. "Investigation of Phospholipid Area Compression Induced by Calcium-Mediated Dextran Sulfate Interaction" <i>Biophys J.</i> 77(2): 879-887 (Aug., 1999).

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EXAMINER INITIAL	OTHER DOCUMENTS (EXCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
WV	Huster et al. "Strength of Ca(2+) Binding to Retinal Lipid Membranes: Consequences for Lipid Organization" Biophys J. 78(6): 3011-3018 (June, 2000).
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WV	Millqvist-Fureby et al. "Surface Characterisation of Freeze-Dried Protein/Carbohydrate Mixtures" Int. J. Pharm. 191: 103-114 (1999).

EXAMINER <i>[Signature]</i>	DATE CONSIDERED <i>12/2/02</i>
*EXAMINER: INITIAL IF CITATION CONSIDERED, WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.	

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APPLICATION NO.

09/886,296

INFORMATION DISCLOSURE STATEMENT
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6/21/200

GROUP
1616

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EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)
	Müllqvist-Fureby et al. "Spray-Drying of Trypsin - Surface Characterisation and Activity Preservation" <i>Int. J. Pharm.</i> 188: 243-253 (1999).
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	Seddon, J.M. "Structure of the Inverted Hexagonal (H_{II}) Phase, and Non-Lamellar Phase Transitions of Lipids" <i>Biochim Biophys Acta</i> 1031: 1-69 (1990). , in particular p. 43-44 and 49-50.

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<p>*EXAMINER: INITIAL IF CITATION CONSIDERED. WHETHER OR NOT CITATION IS IN CONFORMANCE WITH MPEP 609; DRAW LINE THROUGH CITATION IF NOT IN CONFORMANCE AND NOT CONSIDERED. INCLUDE COPY OF THIS FORM WITH NEXT COMMUNICATION TO APPLICANT.</p>	

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JS	1. Joachim Seelig, <i>Handb. Met. -Ligand Interact. Biol. Fluids: Bioinorg. Chem.</i> § Metal Ion Interactions with Lipids: 698-706 (1995)
	Shah et al. "The Ionic Structure of Sphingomyelin Monolayers" <i>Biochim Biophys Acta</i> 135: 184-187 (1967).
	Shavvin et al. "Cholesterol Affects Divalent Cation-Induced Fusion and Isothermal Phase Transitions of Phospholipid Membranes" <i>Biochim Biophys Acta</i> 946: 405-416 (1988).
	Simha et al. "On a General Relation Involving the Glass Temperature and Coefficients of Expansion of Polymers" <i>J. Chem. Physics</i> 37(9): 1003-1007 (Sept., 1962).
BS	Sugisaki et al. "Calorimetric Study of the Glassy State. IV. Heat Capacities of Glassy Water and Cubic Ice" <i>Bulletin of the Chemical Society of Japan</i> 41: 2591-2599 (Nov., 1968).
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12/2 102

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KA	Tetelman, S.A. "Evaluation of Divalent Cation Binding to Phosphatidylserine Membranes by an Analysis of Concentration Dependence Surface Potential" <i>J. Colloid Interface Science</i> 175: 131-137 (1995).
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KA	Yamaguchi et al. "Adsorption of Divalent Cations onto the Membrane Surface of Lipid Emulsion" <i>Colloids and Surfaces B: Biointerfaces</i> 5: 49-55 (1995).

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TRADEMARK OFFICE FORM PTO-1449 U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE INFORMATION DISCLOSURE STATEMENT BY APPLICANT (USE SEVERAL SHEETS IF NECESSARY)	ATTY. DOCKET NO. 0054.10	APPLICATION NO. 09/886,296
	APPLICANT Tarara et al	
	FILING DATE 6/21/02	GROUP 1616

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EXAMINER INITIAL	OTHER DOCUMENTS (INCLUDING AUTHOR, TITLE, DATE, PERTINENT PAGES, ETC.)	
SEA	3.	Zarif, et al. (1999) Amphotericin B cochleates as a novel oral delivery system for the treatment of fungal infections. Proceedings of the International Symposium on Controlled Release Bioactive Materials. pp. 864-865, XP-002145322
SEA		Courtesy copy of PCT International Search Report dated 02/28/02 in 3 pages.

EXAMINER <i>And L</i>	DATE CONSIDERED <i>12/2/02</i>
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